

REMARKS

Applicants have amended the specification to correctly state that the application continues from Application No. 08/873,010. Applicants have included a certificate of correction to correct the continuing data. Applicants have also amended the specification to delete reference to 08/713,834.

The Examiner rejected claims 43-52, 55-62, 65-82 and 85-90 under §112 as failing to comply with the written description requirement. The Examiner states that there is no suggestion that the Vitamin D compounds can be used in non-female subjects or for any other types of cells, other than non-neoplastic ovarian epithelial cells and non-neoplastic breast cells. Applicants submit that based on the teachings of the application, when combined with the information known regarding the Vitamin D receptor, provides sufficient written description. *See Enzo Biochem, Inc. v. Gen-Probe Incorporated*, 323 F.3d 956, 964 (Fed.Cir. 2002); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed.Cir. 2003). Applicants submit that upon reading the specification of Applicants (but only upon such reading), coupled with information regarding the knowledge of cells with Vitamin D receptors, a person skilled in the art could apply the teachings beyond ovarian epithelial cells and breast cells.

The Examiner also rejected claims 35-90 under §112 has not provided enablement for any and all subject or any and all Vitamin D products. The Examiner states that it require undue experimentation to determine which Vitamin D would yield the instant method. Applicants state that methods are well known in the art with respect to testing the apoptotic effect of D compounds. Applicants submit that it would not take undue experimentation to yield the instant method based on the teachings of the application.

The examiner has also rejected claims for doubling patenting. The doubling patenting rejections pertain to U.S. Patent Nos. 6,034,074, 6,407,082 and 6,444,658. Applicants are submitting here concurrently with terminal disclaimers with respect to each of those three patents.

Finally, applicants have amended the specification and the claims to correct a typographical error that repeats eight times in the specification (and several dependent claims). The typographical error appears throughout the patent application whenever dosages of Vitamin D compounds are expressed in gram-type units, specifically “mg” (milligram) units. In all of those instances, the designation “mg” should read “mcg” (micrograms). It would be apparent to a person skilled in the art that this was a typographical error based on a review of both the specification and the 1989 publication of the Food and Nutrition Board of the United States National Research Council, referred to explicitly in the specification.

Specifically, the typographical nature error is shown by the reference in the patent specification to the recommended daily dietary allowances of Vitamin D set forth in the “Food and Nutrition Board of the United States National Research Council from 1989.” On page 4, line 14, to page 5, line 3, of the specification, applicants state:

“Recommended daily dietary allowances of Vitamin D by *the Food and Nutrition Board of the United states National Research Council (1989)* were 10 mg cholecalciferol (400 IU Vitamin D) daily for females age 11-24 and 5 mg cholecalciferol (200 IU Vitamin D) daily for females age 25 and older.”

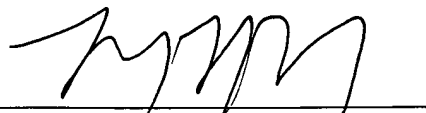
Attached at Tab A is a copy of the “Food and Nutrition Board of the United States National Research Council from 1989” cited in the specification.

As shown in the attached publication of the Food and Nutrition Board of the United States National Research Council, 400 IU Vitamin D correlates to **10 μ g** (mcg or micrograms) of cholecalciferol, not 10 mg. (see Tab A, page 96). Similarly, 200 IU Vitamin D correlates to **5 μ g** (mcg or micrograms) of cholecalciferol, not 5 mg. (see Tab A, page 96). Although not necessary, a quick Google search shows numerous references confirming that 400 IU Vitamin D correlates to 10 mcg of cholecalciferol, and 200 IU Vitamin D correlates to 5 mcg of cholecalciferol.

The typographical error applies to the eight references to Vitamin D dosages in “mg” units in the patent application. A person skilled in the art would recognize that “mcg” was appropriate for all the references to “mg” in the specification given the typo in the correlation of “mg” to IU above and the types of dosages of calcitriol given in the art.

Please charge any fees associated with this filing to Deposit Account No. 10-0460.

Respectfully submitted,



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